of data from industry sources and possibly other stakeholders, in addition to more extensive data collection from State and local agencies.

The sources of this additional information for the refined assessment will vary. It is assumed that State, local, and EPA Regional offices should have information that is more site-specific, especially about which facilities are subject to a particular MACT rule, which have applied for operating permits, and which are in compliance at a particular time. Other facility-specific information that is needed to conduct the more detailed exposure and risk analysis may have to be obtained from the information request mechanisms that were used to gather data for the MACT process. Other information needed may come from existing data bases, such as U.S. Census data, geographic information systems (GIS), or other types of data bases that may provide needed inputs for modeling. EPA may also work together with industry to obtain needed data.

Considerable professional judgment is required to carry out and interpret a more refined residual risk assessment, and the steps taken and approaches used may vary from one source to the next, even within the same source category. As noted earlier, refinement might be necessary for some or all components of the analysis. Evaluating the sensitivity of the risk results to different components of the risk analysis can help identify which components are most important and allow us to preferentially refine the more sensitive components or assumptions.

Human Health

The refined analyses will be based on the methods and approaches described in Chapter 3 and will incorporate more site-specific data, fewer simple default assumptions, and more comprehensive and complex models (e.g., ISCST3 for atmospheric dispersion and deposition). In general, these analyses will be probabilistic and will produce estimates of risk distributions (in addition to point estimates). The theoretical MEI risk estimate will not be used in refined assessments; instead, the MIR estimate for areas that people are believed to occupy will be used to provide input for risk management decisions that may call for additional controls or regulatory actions.

Criteria for Evaluating Refined Analysis Results. The refined analysis, like the screening analysis, may be iterative with increasing complexity at each iteration. General assumptions and criteria are summarized in Exhibit 21. In refined risk assessment, the level of confidence is increased through the use of EPA or comparable consensus toxicity values that reflect currently available information. This ensures that toxicity criteria of consistently high quality and derived by a consistent methodology are used in the assessment. At this level of analysis, additional available credible and relevant data for all toxicity values used will be considered by the Agency. In the exposure assessment, more site-specific data and more refined models are used to estimate exposure concentrations and intakes. In addition, the refined analysis considers the number of people exposed at different levels.

Carcinogens subject to benzene NESHAP. In assessing cancer risk in the refined analysis, multiple HAP exposures are treated as additive where scientifically appropriate or in the absence of information to the contrary (consistent with EPA policy), and the numbers of people exposed in various subpopulation groups may be considered. This is to allow the characterization of risks to specific populations that may need a greater degree of protection. The Agency will evaluate results consistent with the benzene NESHAP, which states that "an MIR of approximately [10^{-4}] should ordinarily be the upper end of the range of acceptability." In addition, EPA would attempt to provide protection to the greatest number of people possible at an excess individual lifetime risk of cancer no higher than one in a million (10^{-6}), taking into account additional factors relating to the appropriate level of control (e.g., costs, economic impacts, feasibility).

Carcinogens for which a margin of exposure analysis is appropriate. For HAPs that EPA has identified as carcinogens with a nonlinear mode of action, consistent with the guidance in EPA's proposed revised cancer guidelines (EPA 1996b) or subsequent final revised guidelines, when available, an MOE analysis may be undertaken.[10] The MOE analysis may take into consideration the number of people exposed, especially sensitive subpopulations, at the various exposure levels. Individual chemical assessments of the "appropriate" MOE may be made, considering factors specific to the individual assessment, which could include any or all of the following: the steepness of the dose-response curve, persistence of the compound in the body, known human variability in response, and demonstrated human sensitivity as compared with experimental animals. In addition, the chemical-specific MOE evaluation should provide information on the appropriate combination or segregation of the chemicals in the mixture. The use of additivity will be maintained, where scientifically appropriate. The methodology for combining chemical-specific MOE values across mixture components has not yet been developed by the Agency. One way this might be done is by first calculating the ratios of individual HAP exposure levels to the corresponding departure point divided by the chemical-specific "appropriate" MOE.[11] These ratios could be summed for multiple chemicals, and a sum of ratios (i.e., total ratio) greater than 1 might be considered indicative of a potential hazard. This is roughly analogous to treating the MOE as a UF and calculating a hazard index.

Non-cancer effects. An RfC that reflects currently available credible and relevant information is preferred for the calculation of an HQ, at this level of analysis. For chemicals

[10] EPA recognizes that the use of an HI approach for non-cancer health effects and a MOE approach for nonlinear carcinogens presents challenges to the economist in performing economics benefits analysis. This concern was raised in the CRARM report, which also discussed a general approach to address the issue (CRARM 1997b). In the coming years, the scientific community will need to work with economists to devise defensible methodologies for economic analyses of these types of effects.

[11] For example, if the departure point for a given chemical is 5 $\mu g/m^3$, the chemical-specific "acceptable" MOE is determined to be 1,000, and the exposure level is 0.0005 $\mu g/m^3$, the ratio for that chemical would 0.0005 ÷ (5/1,000) = 0.1.

with no RfC or if the RfC is not verifiable, a scientifically appropriate alternate value with comparable basis may be used.

For mixtures of HAPs, the HI is calculated based on target organ effects, where adequate data exist to allow such calculations (EPA 1986c; EPA 1997d). For each chemical in the mixture, a thorough review of the toxicity literature may be required to determine which organ systems are affected (e.g., liver, respiratory, central nervous system). It is expected that an HI less than 1 that is derived using target organ specific hazard quotients would ordinarily be considered acceptable. If the HI is greater than 1, then the amount by which the HI is greater than 1, the uncertainty in the HI, the slope of the dose-response curve, and a consideration of the number of people exposed would be considered in determining whether the risk is acceptable.

Evaluation of the acceptable value for an HQ or an HI of 1 also would consider the values of UFs and the confidence in the RfCs that are used in the calculation of the HI. In general, it is considered that each UF is somewhat conservative; because all factors are not likely to simultaneously be at their most extreme (highest) value, a combination of several factors can lead to substantial conservatism in the final value. Larger composite UFs lead to more conservative RfCs. Conversely, lower composite UFs are less conservative and usually indicate a higher level of confidence in the RfC. Intermediate UF values or a mixture of high and low UFs would require an examination of the relative contribution of various chemicals to the HI. Thus, an HI or HQ greater than 1 may be considered acceptable based on consideration of other factors.

The non-cancer acute HQ should be calculated based on estimates of exposure for the appropriate short duration. The ARE, when available, should be used as the chemical-specific health criterion in the calculation of an acute HQ. For chemicals with no ARE, a provisional ARE may be developed from other acute toxicity criteria (see Exhibit 14) or from the available health effects data. For HAP mixtures, the non-cancer acute HI should be calculated, as appropriate, based on estimates of related effects (e.g., in the same target system). On a case-by-case basis, HQs or HIs greater than 1 may be considered acceptable based on consideration of the factors described above for chronic HQs and HIs.

Ecological

For the more refined ecological assessments, spatial and temporal patterns of HAP contamination of the environment and more complete exposure-response profiles will likely be considered. Also, more sophisticated models can be used to simulate the fate and transport of contaminants in the ecosystem of concern, or concentrations in environmental media might actually be measured in the field and mapped to depict the contamination pattern at the specific site.

Natural populations and communities usually can compensate for some degree of loss in survivorship or reproduction. The ability for populations to compensate for some loss depends on species' characteristics (e.g., longevity, growth rate, reproductive rate) and characteristics of

the ecosystem and communities in which the species exists (e.g., food abundance, presence of competitors, natural stress levels). Plants tend to be very resilient and able to tolerate or compensate for a wide range of natural (e.g., drought) and anthropogenic stressors. All "natural" populations and communities undergo changes on at least a seasonal basis, and ecosystems can exist in many different states, all of which might be "healthy" and likely to persist over time. These issues will be important to consider in the development of residual risk methodology for identifying "adverse environmental effects."

Evaluating the sensitivity of the risk results to different components of the risk analysis can help identify which components are most important and allow the assessors to refine the more sensitive analyses or assumptions sequentially. If it appears that some site-specific information will need to be collected in the field (e.g., identify and evaluate the ecosystems surrounding a facility and the pattern of contamination around the facility), the problem formulation step and conceptual model will need to be refined as thoroughly as possible, and an analysis plan should be developed for the field data collection and assessment. During this problem formulation, assessment endpoints may need to be defined on a site-specific basis. It might be possible to identify species that require a higher level of protection (e.g., game fish) than species for which greater functional redundancy exists (e.g., forage fish, for which many species can play a similar functional role in the ecosystem). Moreover, on a site-specific basis, endpoints other than direct toxicological effects might be considered, such as a change in algal species composition in response to a chemical stressor that results in a decline in water quality.

If a refined analysis is needed, more realistic (i.e., less generic) approaches can be used to characterize risks. General assumptions and criteria are summarized in Exhibit 22. For example, in early iterations of the refined analysis, an ecotoxicity criterion may be compared to an average instead of maximum estimated HAP concentration, using an ecologically relevant area over which to average the concentrations. A refined assessment may involve comparing a series of isopleths (i.e., lines of constant concentration) of estimated HAP concentrations in the environment to stressor-response curves. For a refined analysis of a specific site, mapping the overlap of isopleths of estimated or measured HAP concentrations with the location of ecological receptors can be helpful in evaluating the significance of the risks. For example, population-level models might be adapted for an ecological risk assessment application to delineate the impact of a chemical stressor on population dynamics over space and time. Such tools have already been used successfully in ecological risk assessments, particularly for fish populations (see Suter 1993). Information to be included in such refined risk characterizations would also include the local, State, Tribal, regional, and/or national ecological value or significance of the ecological entities at risk.

5.3.6 Risk Management/Risk Reduction Decisions

Prior to a decision on the need for a standard and specifically what that standard needs to accomplish, there are risk management decision points within the residual risk assessment strategy after the risk characterization step in each of the risk assessments (see Exhibit 20). To

consider a source category to be of no further concern under the residual risk program, the health criteria ("ample margin of safety") and, considering costs and other factors, the environmental criteria (no "adverse environmental effect") would need to be satisfied. Where the available information is too limited to make a "no further action" determination, those components of the source category responsible for the uncertainty would be subject to more data collection and more refined analysis. If the decision is made not to continue the analysis of a source category (i.e. that source category is eliminated from further consideration under section 112(f) in this process), then the information supporting that decision would be made available to stakeholders.

While the screening analyses can serve as a basis for a decision to pursue additional analyses or to eliminate low-risk source categories from further consideration under section 112(f), early iterations at the screening tier of analysis are not adequate to serve as a basis for establishing additional emission reduction requirements under section 112(f).

In addition to the results of the risk analysis/characterization based on human health and environmental data, EPA is also required by CAA section 112(f) to consider other factors before the establishment of additional risk standards. In determining whether further regulation is warranted in order to protect public health with an ample margin of safety and/or to prevent an adverse environmental effect, the risk manager will evaluate the level of risk and the risk reduction achievable against costs, feasibility, and other factors and, in the case of environmental risks, against costs, energy, safety, and other relevant factors. The Agency recognizes that because of location (or other factors) there may be cases where, after application of MACT standards, only a subset of facilities within a source category poses risks of concern. In determining the need for additional standards, EPA would look at all federal, State, and local regulations for that particular category. The proposed integrated air toxics budget initiative for fiscal year 2000 is intended to be a significant tool that could be used to achieve additional air toxics reduction beyond MACT control through available authority and approaches prior to residual risk determination. EPA will then evaluate the remaining risk and consider ample margin of safety as discussed below. In those cases where it is determined to be necessary, EPA will use CAA section 112(f)(2) residual risk authority to set national standards but focus the applicability of standards only on those portions of the source category.

The EPA will apply the ample margin of safety framework to public health risks in the context of the tiered risk assessment and management approach for air toxics' residual risks. For carcinogens, EPA will apply a two-step ample margin of safety approach, as described here and in Section 2.1. EPA developed the benzene risk management framework, which forms the basis for human health risk management in the residual risk program, in response to a 1987 DC Circuit Court decision on the Vinyl Chloride national emission standard, also taking into consideration public comment on several alternative risk management approaches it had proposed for benzene (see Section 2.1 for more historical background on the benzene national emission standard). According to the benzene framework, EPA would develop national emission standards for HAPs in two steps: (1) first determine a "safe" or "acceptable risk" level, considering only public health factors, and (2) then set an emission standard that provides an "ample margin of safety"

considering relevant factors in addition to health such as costs, economic impacts, and feasibility. In establishing the acceptable risk level, EPA would consider the extent of the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime, i.e., maximum individual risk (MIR). Although an MIR for cancer of approximately 1 in 10 thousand should ordinarily be the upper-end of the range of acceptability under this approach, EPA would consider other health and risk factors (e.g., projected overall incidence of cancer or other serious health effects within the exposed population, the number of people exposed within each individual lifetime risk range, the science policy assumptions and estimation uncertainties associated with the risk measures). In the second step, EPA would attempt to provide protection to the greatest number of people possible at an excess individual lifetime risk of cancer no higher than 1 in 1 million (10^{-6}), taking into account additional factors relating to the appropriate level of control (e.g., costs, economic impacts, feasibility). The acceptable risk established in the first step would not be exceeded by the standards EPA adopts based on the second step. This approach is consistent with risk management approaches taken by other EPA programs intended to broadly protect public health. For example, other EPA programs use a risk management range of 10^{-6} to 10^{-4} under their reasonable maximum exposure scenario to guide their decision-making for carcinogens.

The EPA has not yet implemented the ample margin of safety approach as interpreted by the Vinyl Chloride decision with respect to non-cancer effects or carcinogens for which the MOE analysis is appropriate, though EPA believes that the 1989 benzene NESHAP could provide important guidance for residual risk decisions in these areas. The Agency does not yet have applications of the benzene NESHAP two-step approach to specifically address non-cancer public health risks and public health risks posed by carcinogens with non-linear risk assumptions, but such risk management framework applications are being developed. In applying the benzene NESHAP approach, the EPA would first determine an "acceptable" level of such risk, again without taking into consideration the cost of achieving such protection or other, non-health factors. As a second step, EPA would set standards sufficient to provide an "ample margin of safety," and these other factors would be weighed in such standard-setting. Under this approach, the Agency would have the discretion under Vinyl Chloride to identify both the "acceptable risk" level and methods of arraying factors for consideration in the "ample margin of safety" step.

Section 112(f) also gives EPA the authority to promulgate more stringent controls as necessary to protect against an adverse environmental effect. In promulgating such controls, EPA must, according to the statute, take into consideration costs, energy, safety, and other relevant factors. The EPA is currently developing a policy for how it will implement this authority and make residual risk management decisions regarding prevention of adverse environmental effects.

5.3.7 Comparison to CRARM Recommendations

In formulating its strategy for assessing residual risks under the CAA, EPA has conformed to many of the specific recommendations articulated by CRARM in their 1997 final report (CRARM 1997a,b). EPA's overall consistency with the tiered approach advocated by the

Commission (see Exhibit 4) is evident throughout this Report in the methods and strategies described (see, for example, Exhibit 20). In addition, five specific recommendations of the Commission (see Section 3.1.2) are listed here along with a short explanation of how EPA is fulfilling each.

- *Characterize and articulate the scope of the national, regional, and local air toxics problems and their public health and environmental contexts.*

  We are in the process of defining an Air Toxics Strategy that will assess what we know about these problems and will identify how the provisions in section 112 can best address them. As part of the air toxics program directed by Congress in the CAA, we have and continue to characterize specific issues such as mercury emissions (EPA 1997a), emissions from utilities (EPA 1998b), and deposition of air pollutants to the Great Waters (EPA 1997b). The integrated Urban Air Toxics Strategy (EPA 1998a), which is focused on risks posed by cumulative emissions in urban areas, and the residual risk program (described in this Report), through which post-MACT risks from industrial source categories are assessed, are two major elements of EPA's characterization of the air toxics problem as part of the air toxics program.

- *Use available data and default assumptions to perform screening-level risk assessments to identify sources with the highest apparent risks.*

  This is the underlying strategy of EPA's residual risk approach described throughout this Report and illustrated in the flow chart in Exhibit 20. The flow chart is an adaptation of the approach proposed by the Commission in their 1997 final report.

- *Conduct more detailed assessments of sources and facilities with the highest risks, providing guidance and incentives to regulated parties to either conduct these risk assessments or reduce emissions to below screening thresholds.*

  EPA is currently evaluating the potential for both EPA and regulated parties to carry out detailed risk assessments, when appropriate based on screening assessment results, using the methods described in detail in Chapter 3 of this Report. EPA will develop guidance for such assessments as necessary.

  EPA will consider incentives to industry to reduce residual risks, as described in Section 4.1.2.

- *At facilities that have incremental lifetime upper-bound cancer risks greater than one in 100,000 persons exposed or that have exposure concentrations greater than reference standards, examine and choose risk reduction options in light of total facility risks and public health context.*

In accordance with CAA section 112(f)(2), EPA will consider the estimated cancer risks for facilities and implement management options that ensure an "ample margin of safety" as defined in the 1989 benzene NESHAP. The two-step benzene approach, described in detail in Section 2.1, is generally consistent with the Commission's recommendation, although it does not incorporate a "flexible bright line" of 10^{-5} (CRARM 1997b). As discussed in Section 5.3.6, the Agency is developing risk management frameworks for non-cancer effects and carcinogens analyzed by an MOE approach.

EPA may consider total facility risks and public health context in risk management decisions when doing so will ensure that the concept of ample margin of safety is maintained.

- *Consider reduction of residual risks from source categories of lesser priority.*

EPA interprets this statement to say that the Agency should address highest risk source categories first, and then consider additional risk reductions from the lower priority (i.e., lower risk) source categories. The Agency will prioritize source categories for evaluation under the residual risk program to the extent possible, given data limitations and legislative time constraints. The goal of prioritizing will be to address source categories with higher risk first. EPA will use information from the Agency's overall air toxics program and data gathered in the problem formulation part of the risk assessments to help prioritize source categories.

An alternative interpretation of this statement is that lesser priority risk sources should not be ignored in the implementation of risk reduction actions. While these sources may not be identified for additional risk reduction requirements under residual risk, they will receive attention, as appropriate, under our broader programs aimed at pollution prevention and waste minimization nationwide.

5.4 Summary

Following the CAA section 112(f), EPA has developed a framework to identify, assess, and manage the residual risks associated with air toxics emissions following the application of MACT standards to source categories. We will be relying on the general methodology and process illustrated by the framework described in this document in our risk assessment activities throughout the air toxics program. The framework is guided by sections 112(f)(2) through (6) and influenced by the recent recommendations made by the NRC (NRC 1994) and the Risk Commission (CRARM 1997a,b), and it incorporates EPA's current risk assessment and risk management policies, published guidelines, and methods. In short, the residual risk analysis framework consists of a tiered, iterative assessment of the human health and environmental risks resulting from both inhalation and non-inhalation exposures to HAPs following MACT implementation, leading ultimately to decisions on whether additional emission reductions are needed. Key steps in the process include problem formulation, data collection, risk analysis, and

risk management/risk reduction decision-making. The human health risk management decision criteria are based on the "ample margin of safety" principles, first laid out in EPA's 1989 national emission standard for benzene and affirmed in the 1990 CAA Amendments, and the environmental decision criteria are based on the "prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect" language in the statute. This framework is intended to provide EPA appropriate flexibility in its decisions while ensuring that public health and the environment are protected from air toxics as envisioned by Congress in the CAA.

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References

Agency for Toxic Substances and Disease Registry (ATSDR). 1993a. Toxicological profile for cadmium. Atlanta: U.S. Department of Health and Human Services, Public Health Service.

Agency for Toxic Substances and Disease Registry (ATSDR). 1993b. Toxicological profile for lead. Atlanta: U.S. Department of Health and Human Services, Public Health Service.

Agency for Toxic Substances and Disease Registry (ATSDR). 1994. Toxicological profile for mercury. Atlanta: U.S. Department of Health and Human Services, Public Health Service.

Agency for Toxic Substances and Disease Registry (ATSDR). 1998. Agency for Toxic Substances and Disease Registry: Minimal risk levels (MRLs) for hazardous substances at http://atsdr1.atsdr.cdc.gov:8080/mrls.html. Updated January 5, 1998.

Agency for Toxic Substances and Disease Registry (ATSDR). 19xx. Toxicological profile for [various substances]. Atlanta: U.S. Department of Health and Human Services, Public Health Service.

American Industrial Hygiene Association (AIHA). 1998. Emergency response planning guidelines and workplace environmental exposure level guides. Fairfax, VA.

Baird, S.J., J.T. Cohen, J.D. Graham, A.I. Shlyakhter, and J.S. Evans. 1996. Non-cancer risk assessment: A probablistic alternative to current practice. Human and Ecological Risk Assessment 2(1):79-102.

Binkova, B., J. Lewtas, I. Miskvova, J. Lenicek, and R. Sram. 1995. DNA adducts and personal air monitoring of carcinogenic polycyclicaromatic hydrocarbons in an environmentally exposed population. Carcinogenesis (England) 16(5):1037-1046.

Bloom, D.L., D.M. Byrne, and J.M. Andresen. 1993. Communicating risk to senior EPA policy makers: A focus group study. Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC.

Bogen, K.T. and R.C. Spear. 1987. Integrating uncertainty and interindividual variability in environmental risk assessment. Risk Analysis 15(3): 411-419.

Brown, L.M., L.M. Pottern, and W.J. Blot. 1984. Lung cancer in relation to environmental pollutants emitted from industrial sources. Environ. Res. 34:250-261.

Bustueva, K.A., B.A. Revich, and L.E. Bezpalko. 1994. Cadmium in the environment of three Russian cities and in human hair and urine. Arch. Environ. Health 49(4):284-288.

Commission on Risk Assessment and Risk Management (CRARM). 1996. Risk assessment and risk management in regulatory decision-making. Draft report. Washington, DC.

Commission on Risk Assessment and Risk Management (CRARM). 1997a. Framework for environmental health risk management. Final report, Volume 1. Washington, DC.

Commission on Risk Assessment and Risk Management (CRARM). 1997b. Risk assessment and risk management in regulatory decision-making. Final report, Volume 2. Washington, DC.

Connell, D.W. 1988. Bioaccumulation behavior of persistent organic chemicals with aquatic organisms. Rev. of Environ. Contamin. and Toxicol. 101:118-154.

Dayal, H., S. Gupta, N. Trieff, D. Maierson, and D. Reich. 1995. Symptom clusters in a community with chronic exposure to chemicals in two Superfund sites. Archives of Environmental Health 50(2):108-111.

Driver, L. and A. Pope. 1998. The 1996 National Toxics Inventory and its role in the Government Performance and Results Act. AWMA/EPA Emission Inventory Conference, New Orleans, LA. December 1998.

Edmonds, L.D., C.E. Anderson, J.W. Flynt Jr., and L.M. James. 1978. Congenital central nervous system malformations and vinyl chloride monoma exposure: A community study. Teratology 17:137-142.

Finkel, A.M. 1990. Confronting Uncertainty in Risk Management: A Guide for Decision-Makers. Center for Risk Management, Resources for the Future. Washington, DC.

Finley, B. and D. Paustenbach. 1994. The benefits of probabilistic exposure assessment: Three case studies involving contaminated air, water, and soil. Risk Analysis 14(1):53-73.

Frey, H.C. 1992. Quantitative analysis of uncertainty and variability in environmental policy making. Prepared for the American Association for the Advancement of Science and the U.S. Environmental Protection Agency.

Frey, H.C. and D.S. Rhodes. 1996. Characterizing, simulating, and analyzing variability and uncertainty: an illustration of methods using an air toxics emissions example. Human and Ecological Risk Assessment 2(4):762-797.

Frost, F., L. Harter, S. Milham, R. Royce, A. Smith, J. Hartley, and P. Enterline. 1987. Lung cancer among women residing close to an arsenic emitting copper smelter. Arch. Environ. Health 42:148-152.

Garten, C.T., Jr. and J.R. Trabalka. 1983. Evaluation of models for predicting terrestrial food chain behavior of xenobiotics. Environ. Sci. Technol. 17(10):590-595.

Hattis, D. and K. Barlow. 1996. Human interindividual variability in cancer risks -- Technical and management challenges. Human and Ecological Risk Assessment 2(1):194-220.

Hoffman, F.O. and J.S. Hammonds. 1994. Propagation of uncertainty in risk assessments: the need to distinguish between uncertainty due to lack of knowledge and uncertainty due to variability. Risk Analysis 14(5): 707-712.

Hughes, J.P., L. Polissar, and G. Van Belle. 1988. Evaluation and synthesis of health effects studies of communities surrounding arsenic producing industries. Int. J. Epidemiol. 17:407-413.

Klemans, W., et al. 1995. Cytogenetic biomonitoring of a population of children allegedly exposed to environmental pollutants. Phase I, SCE analysis. Mutation Research 319(4):317-323.

Lawton, J.H. and V.K. Brown. 1994. Redundancy in ecosystems: Biodiversity and ecosystem function. Springer-Verlag, Berlin Heidelberg, Germany. pp. 255-270.

Maughan, J.T. 1993. Ecological assessment of hazardous waste sites. Van Nostrand Reinhold, New York, NY.

McKone, T.E. 1994. Uncertainty and variability in human exposures to soil contaminants through home-grown food: A Monte Carlo assessment. Risk Analysis 14(4):405-419.

Morgan, G. and M. Henrion. 1990. Uncertainty: A guide to dealing with uncertainty in quantitative risk and policy analysis. Cambridge University Press.

National Academy of Sciences (NAS). 1973. Water quality criteria 1972 (the "Blue Book").

National Research Council (NRC). 1983. Risk assessment in the federal government: Managing the process. National Academy Press, Washington, DC.

National Research Council (NRC). 1986. Criteria and methods for preparing emergency exposure guidance level (EEGL), short-term public emergency guidance level (SPEGL), and continuous exposure guidance level (CEGL) documents. National Academy Press, Washington, DC.

National Research Council (NRC). 1993. Guidelines for developing community emergency exposure levels for hazardous substances. National Academy Press, Washington, DC.

National Research Council (NRC). 1994. Science and judgment in risk assessment. National Academy Press, Washington, DC.

National Research Council (NRC). 1996. Understanding risk. National Academy Press, Washington, DC.

Natural Resources Defense Council (NRDC), Inc. v. EPA. 1987. 824 F.2d at 1146.

Nordstrom, S., L. Beckman, and I. Nordenson. 1978. Occupational and environmental risks in and around a smelter in northern Sweden, variations in birthweight. Hereditas 88:43-46.

Paustenbach, D.J. 1989. The risk assessment of environmental and human health hazards: A textbook of case studies. John Wiley and Sons, New York, NY.

Pershagen, G. 1985. Lung cancer mortality among men living near an arsenic emitting smelter. Am. J. Epidemiol. 122:684-694.

Ries, L.A.G., C.L. Kosary, B.F. Hankey, B.A. Miller, and B.K. Edwards (eds). 1998. SEER cancer statistics review, 1973-1995. National Cancer Institute, Bethesda, MD.

Rosenman, K.D., J.E. Rizzo, M.G. Conomos, and G.J. Halpin. 1989. Central nervous system malformations in relation to polyvinyl chloride production facilities. Arch. Environ. Health 44(5):279-282.

Sheehan, P.J., A. Baril, P. Mineau, D.K. Smith, A. Harfenist, and W.K. Marshall. 1987. The impact of pesticides on the ecology of prairie-nesting ducks. Technical Report Series, No. 19. Canadian Wildlife Service, Ottawa.

Shy, C.M. 1993. Epidemiological studies of neurotoxic, reproductive, and carcinogenic effects of complex mixtures. Environ Health Perspect 101(Suppl. 4):183-186.

STAPPA/ALAPCO. 1989. Toxic air pollutants: State and local regulatory strategies.

Suter, G.W., II. 1993. Ecological risk assessment. Lewis Publishers, Chelsea, MI.

Theriault, G., H. Iturra, and S. Gingras. 1983. Evaluation of the association between birth defects and exposure to ambient vinyl chloride. Teratology 27:359-370.

U.S. EPA. 1976. Quality criteria for water (the "Red Book"). Office of Water, Washington, DC.

U.S. EPA. 1980. Notice of water quality criteria documents. *Federal Register* 45:79318. November 20.

U.S. EPA. 1984. Risk assessment and management: Framework for decision making. Office of Policy, Planning, and Evaluation, Washington, DC. EPA-600/9-85-002.

U.S. EPA. 1986a. Guidelines for mutagenicity risk assessment. *Federal Register* 51:34006-34012. September 24.

U.S. EPA. 1986b. Guidelines for carcinogen risk assessment. *Federal Register* 51:33992-34003. September 24.

U.S. EPA. 1986c. Guidelines for the health risk assessment of chemical mixtures. *Federal Register* 51:34014-34025. September 24.

U.S. EPA. 1986d. Guidelines for deriving numerical water quality criteria for the protection of aquatic organisms and their uses. Office of Water Regulations and Standards, Washington, DC.

U.S. EPA. 1986e. Standard evaluation procedure for ecological risk assessment. Office of Prevention, Pesticides, and Toxic Substances and Office of Pesticide Programs, Washington, DC. EPA-540/9-85-001.

U.S. EPA. 1986f. Guidelines for exposure assessment. *Federal Register* 51:34042-34054. September 24.

U.S. EPA. 1986g. Users manual for the human exposure model (HEM). OAQPS, Research Triangle Park, NC. EPA-540/5-86-001. June.

U.S. EPA, Federal Emergency Management Agency, and Department of Transportation. 1987. Technical guidance for hazards analysis, emergency planning for extremely hazardous substances. EPA-OSWER-88-001.

U.S. EPA. 1988a. Proposed guidelines for exposure-related measurements. *Federal Register* 53:48830-48853. December 2.

U.S. EPA. 1988b. National emission standards for hazardous air pollutants. *Federal Register* 53(145):28496-28056, Proposed Rule and Notice of Public Hearing. July 28.

U.S. EPA. 1989a. National emission standards for hazardous air pollutants; Benzene. Federal Register 54(177):38044-38072, Rule and Proposed Rule. September 14.

U.S. EPA. 1989b. Risk assessment guidance for Superfund, Volume II: Environmental evaluation manual. Office of Emergency and Remedial Response.

U.S. EPA. 1989c. Risk assessment guidance for Superfund, Volume I: Human health evaluation manual. Office of Emergency and Remedial Response.

U.S. EPA. 1990. Methodology for assessing health risks associated with indirect exposure to combustor emissions. Office of Research and Development and Office of Health and Environmental Assessment, Washington, DC. EPA-600/6-90-003.

U.S. EPA. 1991. Guidelines for developmental toxicity risk assessment. *Federal Register* 56:63798-63826.

U.S. EPA. 1992a. Guidelines for exposure assessment. *Federal Register* 57:22888-22938. May 29.

U.S. EPA. 1992b. Framework for ecological risk assessment. Risk Assessment Forum, Office of Research and Development, Washington, DC. EPA-630/R-92-001. February.

U.S. EPA. 1992c. A tiered modeling approach for assessing the risks due to sources of hazardous air pollutants. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA-450/4-9-001.

U.S. EPA. 1992d. Draft report: A cross-species scaling factor for carcinogen risk assessment based on equivalence of $mg/kg^{3/4}$/day. *Federal Register* 57:24152-24173. June 5.

U.S. EPA. 1992e. Guidance on risk characterization for risk managers and risk assessors ("Habicht Memorandum"). Risk Assessment Council, Washington, DC. February 26.

U.S. EPA. 1993a. A review of ecological assessment case studies from a risk assessment perspective. Risk Assessment Forum, Office of Research and Development, Washington, DC. EPA-630/R-92-005. May.

U.S. EPA. 1993b. Addendum to the methodology for assessing health risks associated with indirect exposure to combustor emissions. Office of Research and Development, Washington, DC. EPA-600/AP-93-003.

U.S. EPA. 1993c. A descriptive guide to risk assessment methodologies for toxic air pollutants. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA-453/R-93-038.

U.S. EPA. 1993d. National emission standards for hazardous air pollutants schedule for the promulgation of emission standards under section 112(e) of the Clean Air Act Amendments of 1990. *Federal Register* 58:63941-63954. December 3.

U.S. EPA. 1994a. Deposition of air pollutants to the Great Waters, First Report to Congress. EPA-453/R-93-055. May.

U.S. EPA. 1994b. A review of ecological assessment case studies from a risk assessment perspective, Volume II. Risk Assessment Forum, Office of Research and Development, Washington, DC. EPA-630/R-94-003. July.

U.S. EPA. 1994c. Exposure assessment guidance for RCRA hazardous waste combustion facilities. Office of Solid Waste and Emergency Response, Washington, DC. EPA-530/R-94-021.

U.S. EPA. 1994d. National Human Activity Pattern Survey (NHAPS) – Use of nationwide activity data for human exposure assessment (W.C. Nelson, Project Officer, EPA/ORD, Research Triangle Park, NC). Presented at American Waste Management Association meeting. Cincinnati, OH. Paper #94-WA75A.01. June.

U.S. EPA. 1994e. Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry. Washington, DC.

U.S. EPA. 1994f. Estimating exposure to dioxin-like compounds (three volumes). External review draft. EPA-600/6-88-005Ca.

U.S. EPA. 1994g. Methods for exposure-response analysis and health assessment for acute inhalation exposure to chemicals: Development of the acute reference exposure. Draft Working Paper. Office of Health and Environmental Assessment, Research Triangle Park, NC.

U.S. EPA. 1995a. Guidance for risk characterization. Science Policy Council, Washington, DC. February.

U.S. EPA. 1995b. SCREEN3 model user's guide. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA-454/B-95-004.

U.S. EPA. 1995c. User's guide for the industrial source complex (ISC3) dispersion models. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA-454-/B-95-003a.

U.S. EPA. 1995d. Great Lakes water quality initiative criteria documents for the protection of wildlife: DDT, Mercury, 2,3,6,8-TCDD, PCBs. Office of Water. EPA-820/B-95-008.

U.S. EPA. 1995e. Final water quality guidance for the Great Lakes System. *Federal Register* 60:15366, Final Rule. March 23.

U.S. EPA. 1995f. Policy for risk characterization ("Browner Memorandum"). Office of the Administrator, Washington, DC. March.

U.S. EPA. 1995g. Summary and analysis of available air toxics health effects data. Final draft. Prepared by ICF Incorporated for Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency. September.

U.S. EPA. 1995h. Proposed guidelines for neurotoxicity risk assessment. *Federal Register* 60(192):52032-52056. Office of Research and Development, Research Triangle Park, NC.

U.S. EPA. 1995i. Technical support document for the Hazardous Waste Identification Rule: Risk assessment for human and ecological receptors. Office of Solid Waste. August.

U.S. EPA. 1996a. Hazardous air pollutant list, modification. *Federal Register* 61:30816-30823, final rule. June 18.

U.S. EPA. 1996b. Proposed guidelines for carcinogen risk assessment. Office of Research and Development, Washington, DC. EPA-600/P-92-003C.

U.S. EPA. 1996c. Guidelines for reproductive toxicity risk assessment. EPA-630/R-96-009. September.

U.S. EPA. 1996d. Proposed guidelines for ecological risk assessment. *Federal Register* 61:47552. September 9, 1996. Risk Assessment Forum, Office of Research and Development, Washington, DC. EPA-630/R-95-002B. August.

U.S. EPA. 1996e. Accidental release prevention requirements. *Federal Register* 61:31667-31730. June 20.

U.S. EPA. 1996f. Review of the national ambient air quality standards for ozone: Assessment of scientific and technical information. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA-452/R-96-007

U.S. EPA. 1996g. Summary report for the workshop on Monte Carlo analysis. Risk Assessment Forum, Washington, DC. EPA-630/R-96-010.

U.S. EPA. 1997a. Mercury study report to Congress. EPA-452/R-97-0003. December.

U.S. EPA. 1997b. Deposition of air pollutants to the Great Waters, Second report to Congress. EPA-453/R-97-011. June.

U.S. EPA. 1997c. Guiding principles for Monte Carlo analysis. Risk Assessment Forum, Washington, DC. EPA-630/R-97-001. March.

U.S. EPA. 1997d. Draft guidelines for risk assessment of chemical mixtures. Office of Research and Development, Washington, DC.

U.S. EPA. 1997e. Ecological risk assessment guidance for Superfund: Process for designing and conducting ecological risk assessments. Environmental Response Team, Edison, NJ.

U.S. EPA. 1997f. Methodology for assessing health risks associated with multiple exposure to combustor emissions. Office of Research and Development, Cincinnati, OH. NCEA 0238 (Update to EPA/600/6-90/003).

U.S. EPA. 1997g. Exposure factors handbook. Office of Research and Development, Washington, DC.

U.S. EPA. 1997h. National Advisory Committee for acute exposure guideline levels for hazardous substances. *Federal Register* 62:58839-58851, Notice. October 30.

U.S. EPA. 1997i. Amended proposed test rule for hazardous air pollutants; Extension of comment period. *Federal Register* 62:67465-67485. December 24.

U.S. EPA. 1997j. Health effects assessment summary tables: FY 1997 update. Office of Solid Waste and Emergency Response, Washington, DC. EPA-540-R-97-036.

U.S. EPA. 1997k. Policy for use of probabilistic analysis in risk assessment. Office of the Administrator, Washington, DC. May 15.

U.S. EPA. 1997l. EPA Region 5 risk assessment for the Waste Technologies Industries (WTI) hazardous waste incinerator East Liverpool, Ohio. 8 volumes. Chicago, Illinois. PB97-174486. May.

U.S. EPA. 1997m. National Ambient Air Quality Standards for Ozone. *Federal Register* 62(138):38856-38896. July 18.

U.S. EPA. 1997n. Guidance on cumulative risk assessment, Part 1, Planning and scoping. Science Policy Council, Washington, DC.

U.S. EPA. 1998a. Draft integrated urban air toxics strategy to comply with section 112(k), 112(c)(3) and section 202(l) of the Clean Air Act. *Federal Register* 63:49240. September 14.

U.S. EPA. 1998b. Study of hazardous air pollutant emissions from electric utility steam generating units – Final Report to Congress. EPA-453/R-98-004. February.

U.S. EPA. 1998c. Guidelines for neurotoxicity risk assessment. *Federal Register* 63: 26926. May 14.

U.S. EPA. 1998d. Guidelines for ecological risk assessment. EPA/630/R-95-002f. April 30.

U.S. EPA. 1998e. Revised draft user's guide for the AMS/EPA regulatory model – AERMOD. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

U.S. EPA. 1998f. Human health risk assessment protocol for hazardous waste combustion facilities, Volume I. Office of Solid Waste and Emergency Response. EPA-530/D-98-001A.

U.S. EPA. 1998g. Methods for exposure-response analysis for acute inhalation exposure to chemicals: Development of the acute reference exposure. Review draft. Office of Research and Development, Washington, DC. EPA/600/R-98/051.

U.S. EPA. 1998h. Integrated Risk Information System (IRIS); Announcement of 1998 Program; Request for Information. *Federal Register* 63:75-77. January 2.

U.S. EPA. 1998i. U.S. Environmental Protection Agency: Integrated Risk Information System (IRIS) at http://www.epa.gov/iris. Updated October 5.

U.S. EPA. 1998j. ECOTOX Database (AQUIRE, PHYTOTOX, and TERRETOX). (Database is available to EPA and contractors through on-line connection; updated regularly). Office of Research and Development, National Health and Environmental Effects Research Laboratory, Mid-continental Ecology Division, Duluth, MN.

U.S. EPA. 1999 (in press). National air quality and emissions trends report, 1997. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

Appendix A

Full Text of Clean Air Act Section 112(f)

Appendix A
Full Text of Clean Air Act Section 112(f)

(f) Standard to Protect Health and the Environment. — (1) Report. — Not later than 6 years after the date of enactment of the Clean Air Act Amendments of 1990 the Administrator shall investigate and report, after consultation with the Surgeon General and after opportunity for public comment, to Congress on —

(A) methods of calculating the risk to public health remaining, or likely to remain, from sources subject to regulation under this section after the application of standards under subsection (d);

(B) the public health significance of such estimated remaining risk and the technologically and commercially available methods and costs of reducing such risks;

(C) the actual health effects with respect to persons living in the vicinity of sources, any available epidemiological or other health studies, risks presented by background concentrations of hazardous air pollutants, any uncertainties in risk assessment methodology or other health assessment technique, and any negative health or environmental consequences to the community of efforts to reduce such risks; and

(D) recommendations as to legislation regarding such remaining risk.

(2) Emission Standards. — (A) If Congress does not act on any recommendation submitted under paragraph (1), the Administrator shall, within 8 years after promulgation of standards for each category or subcategory of sources pursuant to subsection (d), promulgate standards for such category or subcategory if promulgation of such standards is required in order to provide an ample margin of safety to protect public health in accordance with this section (as in effect before the date of enactment of the Clean Air Act Amendments of 1990) or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. Emission standards promulgated under this subsection shall provide an ample margin of safety to protect public health in accordance with this section (as in effect before the date of enactment of the Clean Air Act Amendments of 1990), unless the Administrator determines that a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. If standards promulgated pursuant to subsection (d) and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million, the Administrator shall promulgate standards under this subsection for such source category.

(B) Nothing in subparagraph (A) or in any other provision of this section shall be construed as affecting, or applying to the Administrator's interpretation of this section, as in effect before the date of enactment of the Clean Air Act Amendments of 1990 and set forth in the Federal Register of September 14, 1989 (54 Federal Register 38044).

(C) The Administrator shall determine whether or not to promulgate such standards and, if the Administrator decides to promulgate such standards, shall promulgate the standards 8 years after promulgation of the standards under subsection (d) for each source category or subcategory concerned. In the case of categories or subcategories for which standards under subsection (d) are required to be promulgated within 2 years after the date of enactment of the Clean Air Act Amendments of 1990, the Administrator shall have 9 years after promulgation of the standards under subsection (d) to make the determination under the preceding sentence and, if required, to promulgate the standards under this paragraph.

(3) Effective date. — Any emission standard established pursuant to this subsection shall become effective upon promulgation.

(4) Prohibition. — No air pollutant to which a standard under this subsection applies may be emitted from any stationary source in violation of such standard, except that in the case of an existing source —

(A) such standard shall not apply until 90 days after its effective date, and

(B) the Administrator may grant a waiver permitting such source a period of up to 2 years after the effective date of a standard to comply with the standard if the Administrator finds that such period is necessary for the installation of controls and that steps will be taken during the period of the waiver to assure that the health of persons will be protected from imminent endangerment.

(5) Area sources. — The Administrator shall not be required to conduct any review under this subsection or promulgate emission limitations under this subsection for any category or subcategory of area sources that is listed pursuant to subsection (c)(3) and for which an emission standard is promulgated pursuant to subsection (d)(5).

(6) Unique Chemical Substances. — In establishing standards for the control of unique chemical substances of listed pollutants without CAS numbers under this subsection, the Administrator shall establish such standards with respect to the health and environmental effects of the substances actually emitted by sources and direct transformation byproducts of such emissions in the categories and subcategories.

Appendix B

Preamble Excerpts from 1989 Benzene NESHAP

Appendix B
Preamble Excerpts from 1989 Benzene NESHAP

[Full Text of Preamble Sections 1, 2, and 3 Only]

ENVIRONMENTAL PROTECTION AGENCY (EPA)

40 CFR Part 61
National Emission Standards for Hazardous Air Pollutants;
Benzene Emissions from Maleic Anhydride Plants,
Ethylbenzene/Styrene Plants, Benzene Storage Vessels,
Benzene Equipment Leaks, and Coke By-product Recovery Plants

[AD-FRL-3620-4]
RIN 2060-AC41

54 FR 38044

September 14, 1989

ACTION: Final rule

I. Summary of Decisions

Overview

This section provides a description of the EPA's approach for the protection of public health under section 112. In protecting public health with an ample margin of safety under section 112, EPA strives to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million and (2) limiting to no higher than approximately 1 in 10 thousand the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years. Implementation of these goals is by means of a two-step standard-setting approach, with an analytical first step to determine an "acceptable risk" that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime risk (MIR) of approximately 1 in 10 thousand. A second step follows in which the actual standard is set at a level that provides "an ample margin of safety" in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors including costs and economic impacts, technological

feasibility, and other factors relevant to each particular decision. Applying this approach to the five benzene source categories in today's notice results in controls that protect over 99 percent of the persons within 50 kilometers (km) of these sources at risk levels no higher than approximately 1 in 1 million.

A principle that accompanies these numerical goals is that while the Agency can establish them as fixed numbers, the state of the art of risk assessment does not enable numerical risk estimates to be made with comparable confidence. Therefore, judgment must be used in deciding how numerical risk estimates are considered with respect to these goals. As discussed below, uncertainties arising from such factors as the lack of knowledge about the biology of cancer causation and gaps in data must be weighed along with other public health considerations. Many of the factors are not the same for different pollutants, or for different source categories.

Background

On July 28, 1988, EPA proposed decisions on standards under Section 112 for five source categories of benzene. A principal aspect of the proposal, and the basis for the proposed decisions on the source categories, were four proposed approaches for decisions under Section 112 as mandated by the DC Circuit's decision in NRDC v. EPA, 824 F.2d at 1146 (1987) (the "Vinyl Chloride" decision). The Vinyl Chloride decision required the Administrator to exercise his judgment under Section 112 in two steps: first, a determination of a "safe" or "acceptable" level of risk considering only health factors, followed by a second step to set a standard that provides an "ample margin of safety," in which costs, feasibility, and other relevant factors in addition to health may be considered.

The four proposed approaches were designed to provide for consideration of a variety of health risk measures and information in the first step analysis under the Vinyl Chloride decision – the determination of "acceptable risk." Included in the alternative approaches were three that consider only a single health risk measure in the first step: (1) Approach B, which considers only total cancer incidence with 1 case per year (case/year) as the limit for acceptability; (2) Approach C, which considers only the maximum individual risk ("MIR") with a limit of 1 in 10 thousand for acceptability; and (3) Approach D, which considers only the maximum individual risk with 1 in 1 million as the limit. The fourth approach, Approach A, was a case-by-case approach that considers all health risk measures, the uncertainties associated with them, and other health information.

In the second step, setting an "ample margin of safety," each of the four approaches would consider all health risk and other information, uncertainties associated with the health estimates, as well as costs, feasibility, and other factors which may be relevant in particular cases. The proposal solicited comment on each of the approaches as well as other approaches for implementing the Vinyl Chloride decision (53 FR 28511-28532). The Agency received many public comments on the approaches from citizen's groups, companies and industry trade groups,

State and local governments, and individuals. Most of the comments supported either Approach A or D, with little comment in support of Approach B or C.

Selection of Approach

Based on the comments and the record developed in the rulemaking, EPA has selected an approach, based on Approaches A and C but also incorporating consideration of incidence from Approach B and consideration of health protection for the general population on the order of 1 in 1 million from Approach D. Thus, in the first step of the Vinyl Chloride inquiry, EPA will consider the extent of the estimated risk were an individual exposed to the maximum level of a pollutant for a lifetime ("MIR"). The EPA will generally presume that if the risk to that individual is no higher than approximately 1 in 10 thousand, that risk level is considered acceptable and EPA then considers the other health and risk factors to complete an overall judgment on acceptability. The presumptive level provides a benchmark for judging the acceptability of maximum individual risk ("MIR"), but does not constitute a rigid line for making that determination.

The Agency recognizes that consideration of maximum individual risk ("MIR") - the estimated risk of contracting cancer following a lifetime exposure at the maximum, modeled long-term ambient concentration of a pollutant - must take into account the strengths and weaknesses of this measure of risk. It is an estimate of the upperbound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years. As such, it does not necessarily reflect the true risk, but displays a conservative risk level which is an upperbound that is unlikely to be exceeded. The Administrator believes that an MIR of approximately 1 in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors.

In establishing a presumption for MIR, rather than a rigid line for acceptability, the Agency intends to weigh it with a series of other health measures and factors. These include the overall incidence of cancer or other serious health effects within the exposed population, the numbers of persons exposed within each individual lifetime risk range and associated incidence within, typically, a 50 km exposure radius around facilities, the science policy assumptions and estimation uncertainties associated with the risk measures, weight of the scientific evidence for human health effects, other quantified or unquantified health effects, effects due to co-location of facilities, and co-emission of pollutants.

The EPA also considers incidence (the numbers of persons estimated to suffer cancer or other serious health effects as a result of exposure to a pollutant) to be an important measure of the health risk to the exposed population. Incidence measures the extent of health risk to the exposed population as a whole, by providing an estimate of the occurrence of cancer or other

serious health effects in the exposed population. The EPA believes that even if the MIR is low, the overall risk may be unacceptable if significant numbers of persons are exposed to a hazardous air pollutant, resulting in a significant estimated incidence. Consideration of this factor would not be reduced to a specific limit or range, such as the 1 case/year limit included in proposed Approach B, but estimated incidence would be weighed along with other health risk information in judging acceptability.

The limitations of MIR and incidence are put into perspective by considering how these risks are distributed within the exposed population. This information includes both individual risk, including the number of persons exposed within each risk range, as well as the incidence associated with the persons exposed within each risk range. In this manner, the distribution provides an array of information on individual risk and incidence for the exposed population.

Particular attention will also be accorded to the weight of evidence presented in the risk assessment of potential human carcinogenicity or other health effects of a pollutant. While the same numerical risk may be estimated for an exposure to a pollutant judged to be a known human carcinogen, and to a pollutant considered a possible human carcinogen based on limited animal test data, the same weight cannot be accorded to both estimates. In considering the potential public health effects of the two pollutants, the Agency's judgment on acceptability, including the MIR, will be influenced by the greater weight of evidence for the known human carcinogen.

In the Vinyl Chloride decision, the Administrator is directed to determine a "safe" or "acceptable" risk level, based on a judgment of "what risks are acceptable in the world in which we live." 824 F.2d at 1165. To aid in this inquiry, the Agency compiled and presented a "Survey of Societal Risk" in its July 1988 proposal (53 FR 28512-28513). As described there, the survey developed information to place risk estimates in perspective, and to provide background and context for the Administrator's judgment on the acceptability of risks "in the world in which we live." Individual risk levels in the survey ranged from 10^{-1} to 10^{-7} (that is, the lifetime risk of premature death ranged from 1 in 10 to 1 in 10 million), and incidence levels ranged from less than 1 case/year to estimates as high as 5,000 to 20,000 cases/year. The EPA concluded from the survey that no specific factor in isolation could be identified as defining acceptability under all circumstances, and that the acceptability of a risk depends on consideration of a variety of factors and conditions. However, the presumptive level established for MIR of approximately 1 in 10 thousand is within the range for individual risk in the survey, and provides health protection at a level lower than many other risks common "in the world in which we live." And, this presumptive level also comports with many previous health risk decisions by EPA premised on controlling maximum individual risks to approximately 1 in 10 thousand and below.

In today's decision, EPA has selected an approach based on the judgment that the first step judgment on acceptability cannot be reduced to any single factor. The EPA believes that the level of the MIR, the distribution of risks in the exposed population, incidence, the science policy assumptions and uncertainties associated with the risk measures, and the weight of evidence that a pollutant is harmful to health are all important factors to be considered in the acceptability

judgment. The EPA concludes that the approach selected best incorporates all of this vital health information, and enables it to weigh them appropriately in making a judgment. In contrast, the single measure Approaches B, C, and D, while providing simple decision making criteria, provide an incomplete set of health information for decisions under section 112. The Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information. As applied in practice, the EPA's approach is more protective of public health than any single factor approach. In the case of the benzene sources regulated here, more than 99 percent of the population living within 50 km would be exposed to risks no greater than approximately 1 in 1 million; and, the total number of cases of death or disease estimated to result would be kept low.

Under the two-step process specified in the Vinyl Chloride decision, the second step determines an "ample margin of safety," the level at which the standard is set. This is the important step of the standard-setting process at which the actual level of public health protection is established. The first step consideration of acceptability is only a starting point for the analysis, in which a floor for the ultimate standard is set. The standard set at the second step is the legally enforceable limit that must be met by a regulated facility.

Even though the risks judged "acceptable" by EPA in the first step of the Vinyl Chloride inquiry are already low, the second step of the inquiry, determining an "ample margin of safety," again includes consideration of all of the health factors, and whether to reduce the risks even further. In the second step, EPA strives to provide protection to the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million. In the ample margin decision, the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including costs and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors. Considering all of these factors, the Agency will establish the standard at a level that provides an ample margin of safety to protect the public health, as required by section 112. Application of this approach to the five source categories under consideration in this rulemaking is summarized in the following discussions.

Maleic Anhydride Process Vents

Summary of Decision: Benzene is no longer used in the manufacture of maleic anhydride because all plants in the industry have converted their process equipment to the more economical n-butane feed process. Thus, all benzene exposure from this industry has been eliminated, and no Federal regulation is needed. Maleic anhydride plants are, therefore, not discussed in the remaining sections of this notice.

Ethylbenzene/Styrene Process Vents

Summary of Decision: The existing level of control is judged to provide an ample margin of safety. Under existing State requirements, overall current emissions have been reduced

98 percent or more from uncontrolled levels. The present level of emissions are estimated to present an MIR of 2 in 100 thousand and a total nationwide incidence of about 1 case every 300 years (0.003 case/year). Levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above the exposures comparable to the MIR.

Most people exposed to benzene from these sources are exposed to very low risk levels. Specifically, the risk estimates show: (1) About 600 people are exposed to risk levels of about 1 in 100 thousand reflecting 1 cancer case every 5,000 years (0.0002 case/year) and (2) at least 90 percent of the population modeled to 20 km (about 400,000 people) is exposed to risk levels of less than 1 in 1 million, reflecting about 1 cancer case every 300 years (0.003 case/year). It is anticipated that if modeling were conducted to a 50 km radius, the percentage of the exposed population at risks of less than 1 in 1 million would be at least 99. Further reductions would provide only negligible additional risk and emission reductions (less than 1 percent additional control) and would cost approximately $0.2 million per year (1982 dollars), which would be about the same in 1988 dollars.

Benzene Storage Vessels

Summary of Decision: In providing an ample margin of safety for this source category, the final standards require effective controls on storage vessels not already controlled. The final standards would reduce nationwide benzene emissions by an estimated additional 20 to 60 percent beyond the baseline level, which already includes emission reductions for most storage vessels. The MIR after application of the standards is estimated to be 3 in 100 thousand. This reflects a reduction from an MIR range of between 4 in 100 thousand and 4 in 10 thousand without the standards. The estimated cancer incidence would be reduced from the range without the standards of 1 case every 10 to 20 years (0.1 to 0.05 case/year) to 1 case every 25 years (0.04 case/ year). Levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above the exposure level after an ample margin of safety is provided by EPA.

Most people exposed to benzene from this source category would be exposed to very low levels. The standards are estimated to result in an emission level where: (1) No people are exposed to a risk level greater than 1 in 10 thousand, (2) about 100,000 people would be exposed to a risk level between 3 in 100 thousand and 1 in 1 million, and (3) a majority of the modeled population (70 million people, or greater than 99 percent) is exposed to a risk level of less than 1 in 1 million. While EPA was unable to estimate the cancer incidences associated with various risk levels for this source category, the cancer incidences for the higher risk levels would occur very infrequently and for the lower risk levels would occur about once every 25 years (0.04 case/year). To reduce these exposures further, the next most effective level of control would cost an additional estimated $1.2 million per year (1982 dollars) or roughly $1.3 million in 1988 dollars, but it was not chosen because it would not reduce the MIR and would reduce the cancer incidence by only 1 case every 100 years (0.01 case/year).

Summary of the Standards: The final standards require control of all new and existing vessels with capacities greater than or equal to 38 cubic meters (m^3) (10,000 gallons) used to store benzene. The standards do not apply to storage vessels used for storing benzene at coke by-product recovery facilities because they are considered under the coke by-product recovery plant standards. The standards require use of certain kinds of equipment and work practices for each type of benzene storage vessel. The standards require the use of internal floating roofs (IFR's) with continuous primary seals on fixed roof vessels, and improvements to fittings (e.g., gaskets). For external floating roof (EFR) vessels, secondary seals are required. The standards also require periodic inspections of the vessel roofs, seals, and fittings. Detailed summaries of the regulation and changes since proposal are contained in sections IV and V of this notice.

Coke By-product Recovery Plants

Summary of Decision: In providing an ample margin of safety for this source category, the final standards reduce benzene emissions by about 97 percent for affected facilities nationwide. The MIR after application of the standards is estimated to be 2 in 10 thousand and the cancer incidence is about 1 cancer incidence every 20 years (0.05 case/year). This reflects significant risk reduction from the MIR of 7 in 1 thousand and the cancer incidence of 1 cancer incidence every 6 months (about 2 case/year) that are estimated to occur without the standards. Given estimating uncertainties in this case, the MIR level after the standards is comparable to the EPA's benchmark of approximately 1 in 10 thousand. As discussed in Section III of this preamble, EPA views this level as an overstatement of the actual MIR because the emission estimates associated with this level are likely to be overstated. Levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above the exposure level expected after an ample margin of safety is provided by EPA.

Most people exposed to benzene from this source category would be exposed to very low levels. The standards reduce emissions to a level where: (1) Approximately 100 people would be exposed to a risk level between the estimated MIR and about 1 in 10 thousand reflecting about 1 cancer incidence every 5,000 years (0.0002 case/year), (2) about 300,000 people would be exposed to a risk level between 1 in 10 thousand and 1 in 1 million reflecting about 1 cancer incidence every 100 years (0.01 case/year), and (3) a majority of the modeled population (70 million people, or greater than 99 percent) would be exposed to a risk level of less than 1 in 1 million, reflecting about 1 cancer incidence every 25 years (0.04 case/year). To reduce these exposures to the level associated with the next most effective level of control would cost an additional estimated $6 million per year (1984 dollars), which would be roughly $6.6 million in 1988 dollars. Furthermore, it would involve the use of a control technology that may not be technically feasible, and would only provide a small overall risk reduction of about 1 percent, reflecting an estimated cancer incidence of 1 in every 33 years (0.03 case/year). Additionally, there would be no change in the MIR of about 2 in 10 thousand.

Summary of Standards: The final standards require that process vessels and tar storage tanks in furnace and foundry coke by-product recovery plants be enclosed and the emissions ducted to an enclosed point in the by-product recovery process where they will be recovered or

destroyed. This requirement is based on the use of a gas blanketing system. The same requirements also apply to storage tanks for benzene, benzene-toluene-xylene (BTX) mixtures, and light oil in furnace coke by-product recovery plants. To ensure proper operation and maintenance of the system, the standards require semiannual visual inspections and monitoring to detect and repair leaks as well as annual maintenance inspections. The final standards also require that light-oil sumps be completely enclosed; this requirement is based on the use of a permanent or removable cover equipped with a gasket. Semiannual visual inspections and monitoring for leak detection and repair are also required for this source.

The final standards establish a zero emissions limit applicable to naphthalene processing, final coolers, and the associated final-cooler cooling towers at both furnace and foundry plants. The limit is based on the use of a wash-oil final cooler, although other types of systems that achieve the emissions limit can also be used.

The final standards also contain provisions for the control of equipment in benzene service, including pumps, valves, exhausters, pressure-relief devices, sampling connections, and open-ended lines. The leak detection and repair requirements are the same as the requirements in 40 CFR 61 subpart V, and additionally include quarterly leak detection and repair requirements for exhausters. A detailed summary of the regulation can be found in section V of this notice.

Benzene Equipment Leaks

Summary of Decision: The existing standards for this source category (Subpart J of part 61) are judged to provide an ample margin of safety, especially considering the overstatement of emissions. When these standards were issued in 1984, EPA estimated it would reduce emissions by about 70 percent from the level that would occur without the standards. Using these emission estimates (which overstate emissions as discussed in the next paragraph), the MIR was estimated to be 6 in 10 thousand and the incidence was estimated to be 1 case every 5 years (0.2 case/year).

Based on information received in the past year, EPA considers the present level of emissions associated with the existing standards to be substantially lower than previously estimated. Thus the available risk estimates are substantially overstated. The EPA has reached this conclusion after reviewing information demonstrating compliance with the existing standards and new information about emissions from equipment leaks. However, because the changes in the control of equipment leaks, especially leaks of air toxics, and the changes in the analytical tools needed for determining emissions from these sources have occurred very recently, EPA has not been able to develop better estimates of benzene emissions from equipment leaks. If EPA were to roughly estimate emissions based on this information, the resulting MIR would be comparable to the benchmark of approximately 1 in 10,000. (This is discussed further in sections III and IV of this preamble). Levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above current levels of exposure.

Most people exposed to benzene emissions from this source category are exposed to very low risk levels. Even at the estimated emission levels, the existing standards result in: (1)

About 1 million people at a level between 1 in 10,000 and 1 in 1 million with an incidence of 1 case every 25 years (0.04 case/year) and (2) the vast majority of the modeled population (200 million people or greater than 99 percent) is exposed at risks of less than 1 in 1 million with an incidence of 1 case every 5 years (0.2 case/year). If the actual emission rates were known, the exposures would be lower than these estimates. To reduce these exposures further to the next most effective level of emission control would require the use of control technologies that may not be technically feasible at an estimated cost of $52.4 million per year (1979 dollars), which would be roughly $75 million in 1988 dollars.

II. Background

Regulatory Background

In 1977, the Administrator announced his decision to list benzene as a hazardous air pollutant under section 112 of the CAA (42 FR 29332, June 8, 1977). Benzene was determined to be a hazardous air pollutant because of its carcinogenic properties, evidenced by elevated leukemia incidence in populations occupationally exposed. Detailed information about the hazard identification, dose/response assessment, exposure assessment and risk characterization for benzene were presented in the preamble to the policy approaches and standards proposed in July 1988 (53 FR 28496), and will not be repeated in today's notice.

The listing of benzene as a hazardous air pollutant was followed by proposal of standards for benzene emissions from maleic anhydride process vents, EB/S process vents, benzene storage vessels, and benzene equipment leaks in 1980 and 1981 (45 FR 26660, April 18, 1980; 45 FR 83448, December 18, 1980; 45 FR 83952, December 19, 1980; and 46 FR 1165, January 5, 1981). On June 6, 1984, after receipt of comments from industry and members of the public, EPA published a final rule setting emission standards for benzene equipment leaks (49 FR 23498) and published proposed standards for benzene emissions from coke by-product recovery plants (49 FR 23522). On that date, EPA also withdrew its proposed standards for maleic anhydride process vents, EB/S process vents, and benzene storage vessels (49 FR 23558). The withdrawal was based on the conclusion that both the benzene health risks to the public from these three source categories, and the potential reductions in health risks achievable with available control techniques were too small to warrant Federal regulatory action under section 112 of the CAA.

On August 3, 1984, the Natural Resources Defense Council (NRDC) filed a petition for review in the United States Court of Appeals for the District of Columbia Circuit, seeking review of the EPA's three withdrawals of proposed benzene emission standards, and the EPA's final standards for benzene equipment leaks (Natural Resources Defense Council, Inc. v. Thomas, No. 84-1387). On October 17, 1984, NRDC petitioned EPA under section 307(d)(7)(B) of the CAA to reconsider its decisions to withdraw standards for maleic anhydride process vents, EB/S process vents, and benzene storage vessels, and to reconsider the promulgated standards for benzene equipment leaks. The EPA denied this petition on August 23, 1985 (50 FR 34144).

On July 28, 1987, the court handed down an en banc decision in a case concerning the national emission standards under Section 112 for vinyl chloride (Docket No. OAQPS 79-3, Part I, Item X-I-4). The court concluded in Vinyl Chloride that EPA had acted improperly in withdrawing a proposed revision to the standards for vinyl chloride by considering costs and technological feasibility without first determining a "safe" or "acceptable" emission level. In light of the Vinyl Chloride opinion, EPA requested a voluntary remand to reconsider its June 6, 1984, benzene decisions. In an order dated December 8, 1987, the court granted the EPA's motion and established a schedule under which EPA was to propose its action on reconsideration within 180 days of the order and take final action within 360 days of the order. This order was subsequently modified to extend the time for proposal by 45 days and then to establish August 31, 1989, as the deadline for final action. The EPA also decided to reconsider the proposed standards for benzene emissions from coke by-product recovery plants in light of the Vinyl Chloride decision and to publish a supplemental proposal. All of these actions were proposed on July 28, 1988 (53 FR 28496).

Public Participation

A public hearing was held in Washington, DC, on September 1, 1988, and was attended by about 90 people. Oral testimony was presented by 12 organizations and individuals. The public comment period closed on October 3, 1988, with over 200 comments received among the four dockets. The public comment period was reopened from December 15, 1988, to January 30, 1989, based on the EPA's review of the comments and the number of requests for an extension of the comment period. Additional comments were received, raising the combined number of comments to more than 275.

Legal Framework Under Vinyl Chloride

The EPA considers the Vinyl Chloride decision to further define the legal framework for setting NESHAP under Section 112 of the CAA. The court set out a two-step process for EPA to follow in making these judgments: first, determine a "safe" or "acceptable risk" level, and then set standards at the level -- which may be equal to or lower, but not higher than, the "safe" or "acceptable" level -- that protects public health with an ample margin of safety. It should be noted that the Vinyl Chloride court acknowledged that EPA could employ a single step analysis under certain circumstances provided cost and feasibility were excluded from consideration. Vinyl Chloride, 824 F.2d at 1165, n.11.

In Vinyl Chloride, the court acknowledged that judgments by EPA concerning scientific uncertainty are a relevant part of the process for establishing NESHAP. As the court noted, Congress, in directing EPA to set NESHAP, recognized that uncertainties over the health effects of the pollutants complicate the task. Vinyl Chloride, 824 F.2d at 1152. These same uncertainties, according to the court, mean that the Administrator's "decision in this area 'will depend to a greater extent upon policy judgments' to which we must accord considerable deference." Id., 824 F.2d at 1162 (citations omitted).

"Safe" or "Acceptable" Level: The first step is for the Administrator to determine what level of risk to health caused by emissions of a hazardous air pollutant is "safe" or "acceptable." (The court used these terms interchangeably.) The court in Vinyl Chloride explicitly declined to determine what risk level is "acceptable" or to set out the method for determining the "acceptable risk" level. Instead, the court stated that these determinations are within the Administrator's discretion.

The court did, however, provide some guidance on the "safe" or "acceptable risk" determination. To make this judgment, "the Administrator must determine what inferences should be drawn from available scientific data and decide what risks are acceptable in the world in which we live." Id., at 1165. However, the court emphasized that "safe" does not require elimination of all risk. To support these propositions, the court cited Industrial Union Dept., AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 642 (1980) and its statement that "[t]here are many activities that we engage in every day – such as driving a car or even breathing city air – that entail some risk of accident or material health impairment; nevertheless, few people would consider those activities 'unsafe'." Vinyl Chloride, 824 F.2d at 1165. As a final matter, the court said that the Administrator cannot consider costs or technological feasibility in this step.

Ample Margin of Safety: Once an "acceptable risk" level is determined, the second step under Vinyl Chloride is to determine whether the emission levels accompanying that determination should be reduced further in providing an "ample margin of safety." Noting that the purpose of the ample margin of safety requirement is to protect against incompletely understood dangers, uncertainties, and variabilities, the court stated that EPA "may * * * decide to set the level below that previously determined to be safe." The court reiterated that because the assessment of risk is uncertain, "the Administrator must use his discretion to meet the statutory mandate." The court added that it is at this stage of the standards-setting process that EPA may consider costs and technological feasibility and other relevant factors: "Because consideration of these factors at this stage is clearly intended to 'protect the public health,' it is fully consistent with the Administrator's mandate under section 112." Vinyl Chloride, 824 F.2d at 1165.

Uniqueness of Decision: The effect of the Vinyl Chloride decision is to require a decision making process for public health protection decisions unique to section 112, and unlike any other regulatory decision faced by EPA. This is the result of the court's prescription of two separate steps for decision making, the first in which only health factors can be considered in setting an acceptable risk level, and the second in which additional factors including cost, technological feasibility, and other relevant factors may be considered in providing an ample margin of safety. This scheme is unlike any other under the CAA itself, or any of the other statutes administered by EPA because the acceptable risk that EPA adopts in the first step cannot be exceeded by the standards EPA adopts in the second step. Thus, the EPA's approach to regulating hazardous air pollutants under section 112 is not applicable to regulatory decisions under other statutes or other sections of the CAA. Regulatory decisions under other statutes or other sections of the CAA will continue to be made using individual deliberative processes pursuant to those distinct statutory mandates.

In contrast to section 112, other EPA statutes have very different structures and legal requirements for decision making on public health standards. For example, while the Safe Drinking Water Act provides for two separate decisions, the first is a purely health-based goal toward which to work, but not necessarily meet; the second is an enforceable standard that is based on cost and feasibility considerations. Under both the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the balancing of health concerns and benefits of continued chemical use, and control costs are explicitly provided for in decision making. The Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act both require statutory decision making very different from the bifurcated process mandated by the court for Section 112.

Prior to issuance of Vinyl Chloride decision by the DC Circuit Court, the EPA's recent judgments under section 112 were made in integrated approaches that considered a range of health and risk factors, as well as cost and feasibility in certain cases. However, the Vinyl Chloride decision has required a change in the EPA's approach to section 112, since the previously employed integrated approaches did not partition consideration of health factors into a first step separate from consideration of the other relevant factors. Thus, the Vinyl Chloride decision requires EPA to consider whether a risk is acceptable without at the same time considering benefits of the activity causing risk, feasibility of control, or other factors that EPA (or anyone) would normally consider in determining whether a risk was "acceptable."

III. Application of Policy to Benzene Source Categories

Introduction

This section of the preamble explains the application of the EPA's policy for the regulation of the benzene source categories discussed in the July 28, 1988, proposal (53 FR 28496). For each source category, the following are provided: (1) Background information particularly noting any changes to the EPA's risk assessment since the July 1988 proposal, (2) the decision on the acceptable risk noting the health-related factors and uncertainties associated with the EPA's decision, and (3) the decision on the ample margin of safety noting health-related impacts, technological feasibility, and cost information associated with this decision. For those sources for which EPA made decisions that result in additional regulatory requirements, the requirements are explained in Section V of this notice.

Ethylbenzene/Styrene Process Vents

Background: This source category covers process vents of plants manufacturing ethylbenzene, styrene, or both. (Benzene emissions from equipment leaks and storage vessels at EB/S plants have been considered separately and are not included in this source category). As of 1985, there were 13 plants in this source category. Information received during the public

comment period indicates that emissions have declined since 1985 and emissions are now estimated to be 135 megagrams per year (Mg/yr) or less.

Decision on Acceptable Risk: The baseline MIR of 2×10^{-5} is below the presumptive benchmark of approximately 1×10^{-4} (which is 1 in 10 thousand expressed in scientific notation). In estimating these risk levels, EPA has not found that co-location of EB/S plants significantly influences the magnitude of the MIR or other risk levels. The nationwide incidence of cancer from exposure to emissions from these facilities is estimated to be about 1 case every 330 years (0.003 case/year) or lower. The majority (more than 90 percent) of the population within 20 km of these sources is exposed to risk levels lower than 1×10^{-6} . For exposures to risk levels greater than 1×10^{-6}, the incidence is estimated to be 1 case every 10,000 years (0.0001 case/year). Benzene concentrations reported to produce noncancer health effects are at least three orders of magnitude above the exposures predicted from these sources. After considering all these factors, EPA judged the emission level associated with an MIR of 2×10^{-5} is acceptable.

Decision on Ample Margin of Safety: The EPA considered selecting a control level more stringent than the level associated with the acceptable risks. This option would require control of the few remaining uncontrolled intermittent emission sources using 98-percent efficient combustion devices (e.g., boilers and flares). In comparing this control option and the existing level of control, EPA found that they provide essentially the same level of safety. Both control levels reflect a significant reduction in risks and emissions from the uncontrolled level. Control of these sources would further reduce benzene emissions by approximately 70 to 90 Mg/yr at most and would reduce the estimated MIR from 2×10^{-5} to 1×10^{-5}. The annual incidence would be reduced by about 1 case every 500 years (0.002 case/year).

The number of people exposed at risks greater than 1×10^{-6} is essentially the same between these two control levels. For the total population exposed to these sources, the incidence would change from 1 case every 330 years (0.003 case/year) to 1 case every 1,000 years (0.001 case/year). Essentially all (95 percent) of this additional reduction in incidence occurs in the population exposed to risks lower than 1×10^{-6}. The proportion of the population at risk levels below 1×10^{-6} is not changed by this emission reduction. In addition, benzene concentrations reported to produce noncancer health effects are at least three orders of magnitude above the exposures predicted for these sources.

As noted above, this control option will reduce benzene emissions by 70 to 90 Mg/yr, which represents less than an additional 1 percent reduction over the uncontrolled level. The cost of this additional emission reduction (and consequent risk reduction) would be about $200,000/yr (1982 dollars). While this additional cost is small, it is disproportionately large in comparison to the small additional emission and risk reduction achieved.

After considering all of these factors, EPA judged that the existing level of controls provides an ample margin of safety. In addition, EPA decided not to set standards to mandate the existing level of controls. Existing controls in the EB/S industry are in the form of product recovery devices or the routing of emissions to the process unit's boilers or other boilers onsite to

conserve energy (less fuel would be required due to the energy content of the waste stream). Thus, there is no incentive for removal of existing controls.

Additionally, there is no incentive for new sources to waste product or energy, and major new sources would be subject to other EPA requirements (e.g., new source review [NSR], prevention of significant deterioration [PSD]). Thus, less effective controls are not expected in the future. For these reasons, EPA has concluded that Federal standards mandating these controls are not warranted.

Benzene Storage Vessels

Background: This source category covers vessels used to store benzene. These vessels are typically located at petroleum refineries, chemical plants, and bulk storage terminals. As of 1984, 126 facilities with benzene storage vessels had been identified. As noted in the July 28, 1988, Federal Register notice, nationwide baseline (i.e., no NESHAP) emissions from benzene storage vessels are estimated to be about 620 to 1,290 Mg/yr. The range of emissions reflects uncertainty about the presence of shingled seals versus continuous seals on existing vessels with IFR's; the lower end of this range reflects the assumption that all storage vessels have continuous seals, while the upper end is based on the assumption that some vessels (17 percent of the existing IFR vessels) are equipped with shingled seals, which emit more benzene than continuous seals. The baseline incidence associated with these emission estimates is estimated to be 1 case every 10 to 20 years (0.1 to 0.05 case/year). The baseline MIR ranges from 4×10^{-5} to 4×10^{-4}.

Decision on Acceptable Risk: The baseline MIR (4×10^{-5} to 4×10^{-4}), while ranging above the presumptive risk of approximately 1×10^{-4}, is judged to be within the acceptable range after consideration of the following factors.

First, the upper end of the range (4×10^{-4}) is very likely an overestimate of the MIR because it assumes that all storage vessels have shingled seals at the plants that would also have the highest MIR's if all vessels in the industry had continuous seals. Based on information received from industry in 1978, EPA estimated that 12 percent of the nationwide benzene storage capacity was in vessels with shingled seals. This was estimated to be only about 17 percent of the existing IFR vessels that store benzene. The EPA believes that shingled seals have not been installed on new vessels for the past several years as general industry practice. Accordingly, the number of vessels equipped with shingled seals is decreasing over time; consequently the associated risk is also decreasing as existing vessels are replaced by new vessels. Therefore, the assumption that all vessels in the worst-case plant have shingled seals for the upper end of the MIR range is a unique conservative assumption for this source category. In addition, the emission estimate for storage vessels equipped with shingled seals is overstated for the following reason. The only test series of IFR vessels with shingled seals had testing irregularities, resulting in inaccurately high emission estimates. These test irregularities are described in detail in the EPA document "Benzene Emissions from Benzene Storage Tanks -- Background Information for Proposal to Withdraw Proposed Standards" (EPA-450/3-84-004, March 1984). Because there is

no way to determine the proportion of emissions attributable to the use of shingled seals versus the test methodology, the emission estimate for shingled-seal vessels continues to reflect all the uncertainty from that test series (49 FR 23563, June 6, 1984). While EPA is unable to quantify these uncertainties, EPA qualitatively considered the effect of these uncertainties (as well as other uncertainties in its risk assessment) in its judgment of acceptability.

Second, even if the MIR were not overestimated, EPA estimated that only 10 people (out of the total modeled population of 70 million) are at risks greater than or equal to 1×10^{-4}, and virtually no cancer incidence is associated with this risk level. In estimating these risk levels, EPA has not found that co-location of plants significantly influences the magnitude of the MIR or other risk levels. Where two or more of the model plants used for the analysis might occur at one site (e.g., both a producer and a consumer of benzene), the risks were calculated from their total emissions. In addition, EPA estimated that the majority of the people (about 99 percent) exposed to benzene from this source category would be exposed to a risk level of less than 1×10^{-6}, reflecting 1 cancer incidence every 12 years (0.08 case/year), and that 900,000 people would be exposed at a risk level between 1×10^{-4} and 1×10^{-6}, reflecting 1 cancer incidence every 50 years (0.02 case/year). The baseline incidence is estimated to be 1 incidence every 10 to 20 years (0.1 to 0.05 cancer case/year). This range reflects the range of emission estimates (620 to 1,290 Mg/yr). Virtually all of the incidence is associated with the population at a risk of less than 1×10^{-5}. Thus, even though one end of the range of the EPA's MIR estimate for this source category is above 1×10^{-4}, it is important to consider that almost all of the exposure to benzene from storage vessels is associated with risks well below the benchmark of approximately 1×10^{-4}.

The EPA also considered the noncancer health effects associated with benzene exposures at levels comparable to the baseline MIR range. Noncancer health effects have been associated with exposure to benzene, but the levels reported to produce such effects are two to three orders of magnitude above exposures comparable to the MIR range of 4×10^{-5} to 4×10^{-4}, especially with the likely overstatement of the top end of the range.

After considering all these factors, EPA judged that the baseline emission level is acceptable.

Decision on Ample Margin of Safety: The EPA considered selecting a level of emissions more stringent than the level associated with acceptable risk in providing an ample margin of safety for this source category. This would require all vessels to have emission reduction equipment that many vessels already have. Specifically, it would require the use of an IFR with continuous primary seals on each existing fixed roof vessel, and more effective continuous primary seals on any new vessel with an IFR. It would also require improvements to fittings (e.g., gaskets) on the roofs of all IFR vessels. On each vessel with an EFR, this option would require secondary seals. These are similar controls to those that are required for volatile organic liquid (VOL) storage vessels (including benzene vessels) in 40 CFR 60 Subpart Kb, which affects vessels constructed or rebuilt after July 23, 1984. This level of control was labeled Option 2 in the July 28, 1988, proposal (53 FR 28496).

Control Option 2 would reduce the estimated MIR to 3 X 10^{-5} from the baseline range of 4 X 10^{-5} to 4 X 10^{-4}. Because no facility could have vessels with shingled seals, which represent the upper end of the baseline range, all vessels would be required to have continuous seals under the control option and the risks are not expressed as a range. Thus, no one would be potentially exposed to a risk of greater than or equal to 1 X 10^{-4}. The number of people estimated to be exposed to a risk level between 1 X 10^{-4} and 1 X 10^{-6} would be reduced from 900,000 at baseline to 100,000 with this control option. The majority of the modeled exposed population (greater than 99 percent) would be exposed to a risk level less than 1 X 10^{-6} with Option 2. While EPA was unable to estimate the cancer incidences associated with various risk levels after control to this option for this source category, the cancer incidences for the higher risk levels would occur infrequently, and for the lower levels would occur about once every 25 years (0.04 case/year). Overall, the total nationwide incidence would be reduced from a range of 1 incidence every 10 to 20 years (0.1 to 0.05 case/year) to 1 incidence every 25 years (0.04 case/year). In addition, levels of benzene reported to produce noncancer health effects are at least three orders of magnitude above the levels expected under Option 2.

Control Option 2 would reduce benzene emissions by a range between 20 to 60 percent (110 to 780 Mg/yr) in comparison to the emissions without standards. To achieve this emission reduction (and consequent risk reduction) would cost $0.1 million/yr (1982 dollars). This cost is considered to be relatively small.

The EPA also considered a more stringent control level, which would require the controls in Option 2 and additionally require secondary seals for IFR vessels (Option 1 in the July 28, 1988, proposal notice, 53 FR 28496). This additional control would not result in any additional reduction in the MIR beyond that achieved by Option 2. The number of people estimated to be exposed to a risk level greater than 1 X 10^{-6} is estimated to be reduced from 100,000 (Option 2) to 80,000 (Option 1). In both cases, the vast majority of the exposed population (greater than 99 percent) is at a risk of less than 1 X 10^{-6}. Overall, the total nationwide incidence would only be reduced from 1 incidence every 25 years (0.04 case/year) for Option 2 to 1 incidence every 33 years (0.03 case/year) for Option 1. This additional incidence reduction is associated mainly with the population exposed to risk levels below 1 X 10^{-6}. Levels of exposure reported to produce noncancer health effects are at least three orders of magnitude above the levels of exposure expected for Option 1, just as for Option 2. The additional cost of Option 1 over Option 2 would be $1.2 million/yr (1982 dollars).

Based on the factors discussed above, EPA decided that the level of control reflected by Option 2 provides an ample margin of safety. Although the emissions associated with the baseline risks are considered to be acceptable, they can be reduced further, achieving additional risk reductions, at a reasonable cost using the control technology included in Option 2. Selecting Option 2 also ensures that any existing shingled seals are replaced with continuous seals, thus addressing one of the uncertainties associated with the EPA's risk assessment. In addition, EPA concluded that additional controls beyond Option 2 are not warranted. The costs of additional controls beyond Option 2 are disproportionately high considering the small reductions in risk and incidence which are achievable.

Coke By-product Recovery Plants

Background: The risk analysis was revised after the July 1988 proposal based on comments that the industry's operating status should be updated. There are now 36 coke by-product recovery plants. The nationwide baseline benzene emissions are estimated to be 17,000 Mg/yr. The revised baseline estimates of health risk indicate an MIR of 7×10^{-3} and an annual cancer incidence of 1 case every 6 months (2 cases/year). More information regarding the updated estimates can be found in Section IV of this preamble and in the BID.

Decision on Acceptable Risk: The baseline risk of 7×10^{-3} is unacceptable for benzene, a known human carcinogen. In considering the decision on acceptable risk for this source category, EPA focused on control to a level that would result in an estimated MIR of 2×10^{-4}. The EPA considers this MIR to be in the acceptable range after considering several factors.

First, the long-term emissions and, therefore, the MIR are likely to be overstated because EPA assumed that coke batteries operate at full capacity for 70 years. In fact, presently not all plants are continuously operating at full capacity (including some of the plants with the highest risks). In addition, the decline in the domestic coke industry makes it likely that the EPA's estimate overstates the long-term emissions. There is considerable uncertainty in predicting the utilization of coke batteries. Therefore, EPA made the assumption of full capacity for 70 years, recognizing the effect of this assumption (as well as other assumptions) on its risk assessment. Thus, EPA believes the MIR is not likely to be much different than the benchmark of approximately 1×10^{-4} even though EPA is unable to quantify these uncertainties and, therefore, adjust the MIR for this source category. However, EPA considered this likely overestimation qualitatively in its judgment of acceptability. Furthermore, over time, the residual emissions from one group of sources in this category (equipment leaks) may decrease as operators use better equipment (e.g., improved valve packing) in addition to the required work practice program.

Second, EPA estimated that 100 people (out of the total modeled population of 70 million) potentially would be exposed to risks of 1×10^{-4} or greater, with 1 cancer incidence every 5,000 years among this group of 100 people (0.0002 case/year). In estimating these risk levels, EPA has not found that co-location of coke by-product recovery plants significantly influences the magnitude of the MIR or other risk levels. In addition, EPA estimated that the vast majority of the modeled population (greater than 99 percent) exposed to benzene from this source category would be exposed to a risk level of less than 1×10^{-6} reflecting 1 cancer incidence every 25 years (0.04 case/year), and that 300,000 people would be exposed at a risk level between 1×10^{-4} and 1×10^{-6} reflecting 1 cancer incidence every 100 years (0.01 case/year). Of the total cancer incidence (1 cancer incidence every 20 years, i.e., 0.05 case/year), 80 percent is associated with the large population at risks of less than 1×10^{-6}. Thus, even though EPA estimates an MIR of about 2×10^{-4} for this option, it is important to consider that almost all the exposure to benzene from this source category is associated with risks well below the benchmark of approximately 1×10^{-4}.

The EPA also considered the noncancer health effects associated with benzene exposures at levels comparable to an MIR level of 2 X 10^{-4}. Noncancer health effects have been associated with exposure to benzene, but the probability is unlikely of the effects occurring at exposures comparable to an MIR level of 2 X 10^{-4}. Levels of benzene reported to produce such effects are three orders of magnitude higher than the concentrations comparable to an MIR of 2 X 10^{-4}.

After considering all these factors, EPA judged the emission level associated with an MIR of 2 X 10^{-4} to be acceptable.

Decision on Ample Margin of Safety: The EPA considered selecting a level of emissions more stringent than the level associated with acceptable risks in providing an ample margin of safety for this source category. This option (Option 1) would require additional control over the acceptable risk level (Option 2) of storage vessels at foundry coke by-product recovery plants and would also require use of dual mechanical seals on pumps and sealed bellows valves (i.e., assumed to be 100 percent control) at both furnace and foundry coke by-product recovery plants. The control technologies and their estimated impacts are presented for each emission point in Table 1 for Options 1 and 2. It should be noted that EPA has not concluded that leakless valves/sealed bellows valves will always effectively eliminate emissions or that they are available for all sizes and types of equipment in benzene service. Nevertheless, EPA evaluated Option 1 to determine if it should be selected to reflect an ample margin of safety even though there would be technological feasibility issues in implementing this option.

Table 1 – Controls Included in Each Option[a]

Emission points	Control technology efficiency (%)	Option 1		Option 2	
		Furnace	Foundry	Furnace	Foundry
Final cooler, cooling tower; napthalene processing/handling	Wash-oil final cooler (100)	X	X	X	X
Tar decanter, tar intercepting sump and flushing-liquor circulation tank	Gas blanketing (98[b])	X	X	X	X
Tar storage and tar-dewatering tanks	Gas blanketing (98)	X	X	X	X
Light-oil condenser, light-oil decanter, wash-oil decanter, and wash-oil circulation tanks	Gas blanketing (98)	X	X	X	X
Excess ammonia-liquor storage tank	Gas blanketing (98)	X	X	X	
Light-oil and BTX storage tanks	Gas blanketing (98)	X	X	X	
Benzene storage tanks	N 2 gas blanketing (98)	X	X	X	
Light-oil sump	Cover (98)	X	X	X	X
Pumps	Monthly inspections (83)			X	X
	Dual mechanical seals (100)	X	X		
Valves	Monthly inspections (73)			X	X
	Sealed-bellows valves (100)	X	X		
Exhausters	Quarterly inspections (55)			X	X
	Degassing reservoir vents (100)	X	X		
Pressure-relief devices	Rupture disc system (100)	X	X	X	X
Sampling connection systems	Closed-purge sampling (100)	X	X	X	X
Open-ended lines	Cap or plug (100)	X	X	X	X

[a] The control options analyzed to determine an ample margin of safety are the same as those analyzed for the July 1988 proposal (53 FR 28496), except that control options less stringent than Option 2, the level determined to be in the acceptable range, are not shown on the table. The impacts associated with these control options have been revised since the July 1988 proposal to reflect updated information on the industry operating status. These revisions are explained in greater detail in Section 6 of the BID.

[b] 95-percent efficiency for tar decanter.

In comparing Options 1 and 2, EPA found that they provide essentially the same level of safety. Each reflects significant risk reduction in comparison to the baseline risks. Although the estimated number of people exposed to a risk level greater than or equal to 1 X 10^{-4} would be reduced from 100 to 50 under Option 1, EPA estimates that Option 1 would not reduce the MIR below the Option 2 level of 2 X 10^{-4}. The number of people exposed to a risk level between 1 X 10^{-4} and 1 X 10^{-6} would be reduced from 300,000 to 200,000 under Option 1. Under both options, the vast majority of the exposed population (greater than 99 percent) would be at risk levels of less than 1 X 10^{-6}. For the population exposed to a risk level between 1 X 10^{-4} and 1 X 10^{-6}, the incidence would change from 1 case every 100 years (0.01 case/year) under Option 2 to 1 case every 140 years (0.007 case/year) under Option 1; for the population exposed to risks below 1 X 10^{-6}, the incidence would change only from 1 case every 25 years (0.04 case/year) under Option 2 to 1 case every 33 years (0.03 case/year) under Option 1. Overall, the total nationwide incidence would be reduced from 1 case every 20 years (0.05 case/year) to 1 case every 33 years (0.03 case/year) or only by an additional 0.02 case/year. Most (about 80 percent) of this additional reduction in incidence in Option 1 compared to Option 2 occurs in the population exposed to risks in the 1 X 10^{-6} range or lower. In addition, levels reported to produce noncancer health effects are about three orders of magnitude above levels expected under either option.

Option 1 reduces benzene emissions by about 98 percent, whereas Option 2 reduces benzene emissions by about 97 percent in comparison to the emissions that would occur without the standards. This reflects only an additional 1 percent reduction for Option 1. Also, the relative difference between these options may be even smaller than estimated. This is due to the uncertainty that sealed bellows valves would actually achieve the assumed 100 percent reduction in Option 1 and the potential for higher emission reduction than estimated for the equipment leak detection and repair program under Option 2. To achieve this emission reduction (and consequent risk reduction), Option 1 would increase the annualized cost by about $6 million/yr (1984 dollars). While this additional cost is relatively small overall, it is disproportionately large in comparison to the small additional emission and health risk reductions associated with Option 1 in comparison to Option 2.

In conclusion, EPA decided that Option 2 provides an ample margin of safety. The EPA judged the risk reductions for Options 1 and 2 to be essentially the same and the greater control cost of Option 1 to be high in relation to the small additional emission and risk reduction achieved. In doing so, EPA considered the likely overstatement of long-term emissions and risks and the question of technical feasibility.

Benzene Equipment Leaks

Background: This source category covers emissions of benzene from pieces of equipment handling process streams that contain greater than 10 percent benzene, by weight. These equipment pieces include pumps, pipeline valves, open-ended valves, flanges, compressors, pressure-relief valves, sampling connections, process drains, and product accumulator vessels. In 1984, there were an estimated 131 facilities in this source category.

When Subpart J of Part 61, the benzene equipment leaks NESHAP, was promulgated in 1984, EPA estimated that this regulation would reduce emissions from about 7,900 Mg/yr to 2,500 Mg/yr (a 69 percent reduction). As noted in the July 28, 1988, Federal Register notice, EPA viewed the estimate of 2,500 Mg/yr for current emissions as being an upperbound estimate, and recognized that actual emissions may be substantially lower. The EPA reached this conclusion after reviewing compliance report information from facilities subject to the existing standards and other information for facilities handling toxic compounds. Information obtained since proposal has further substantiated this conclusion. The basis for this conclusion is summarized below and is discussed in more detail in section IV and in the BID.

During the consideration of the public comments, EPA examined compliance reports from 1987 and 1988 for a randomly-selected sample of 25 facilities subject to the benzene NESHAP. This review showed many facilities had no leaking valves or pumps (0.0 percent) and no facilities had more than 1.5 percent leaking valves. The average leak rate for valves was 0.27 percent. This performance is better than an average expected leak rate of about 3 to 5 percent. In addition to the compliance reports, EPA also reviewed a limited amount of comprehensive data for a few process units with equipment in benzene service. These data show emission rates a factor of 20 to 30 below levels predicted by the earlier EPA studies. However, these more recent results do not provide a basis for developing new emission factors that would be generally applicable to all facilities. To rederive the emission estimates will require additional information and analysis of current industry practices. As this information has been received only recently, EPA has not been able to conduct the necessary studies and analyses in time to revise the emission estimates for benzene equipment leaks. The EPA has initiated a negotiated rulemaking to develop a new regulatory approach that will result in quantifiable emission levels, give credit for good original plant design, and motivate innovation (54 FR 17944, April 25, 1989). This effort is expected to require at least 6 months to complete. Consequently, the emission and risk estimates remain essentially as presented in the July 28, 1988, Federal Register notice.

Decision on Acceptable Risk: Based on 1984 emission estimates, the MIR is estimated to be 6×10^{-4}. However, as discussed previously under "Background" (and as discussed in detail in section IV, in response to comments), EPA considers the emission estimates to be overstated by roughly a factor of 5 to 20, or more. If actual emissions could be quantified and modeled in the exposure analysis, the risk estimates would decrease proportionately to the emissions, and would be comparable to the presumptive risk benchmark. An additional factor in this overstatement of emissions is that the analysis was developed assuming facilities continued to operate at the estimated emission rate for 70 years. However, EPA expects that, over time, emissions may continue to decrease due to improved control of air toxics through use of better design, operation, and maintenance of facilities. Given all these factors, EPA concludes that the MIR for this category is more likely to be less than the benchmark of approximately 1×10^{-4}, and will use this in its judgment on acceptability.

The estimated annual cancer incidence (based on the overstated emission estimates) is 1 case every 5 years (0.2 case/year) in a total modeled population of 200 million. The estimated incidence among the 2,000 people predicted to be at lifetime risks greater than 1×10^{-4} is only 1

case every 200 years (0.005 case/year). In estimating these risk levels, EPA has not found that co-location of facilities significantly influences the magnitude of the MIR. In addition, EPA estimated the majority of the population (greater than 99 percent) exposed to benzene from this source category would be exposed to risk levels below 1 X 10^{-6}. The incidence predicted for the population exposed to risks smaller than 1 X 10^{-6} is 1 case every 5 years (0.2 case/year), and the incidence for the population exposed to risks greater than 1 X 10^{-6} is 1 case every 20 years (0.05 case/year).

The EPA also considered the noncancer health effects associated with benzene exposures at current levels of exposure from this source category. Benzene concentrations reported to produce noncancer health effects are two to three orders of magnitude above the exposures predicted for these sources.

After considering all of these factors, especially the substantial overstatement of emissions, EPA judged that the present, controlled level of emissions and risks are acceptable.

Decision on Ample Margin of Safety: The EPA considered selecting a level of emissions more stringent than the level associated with the existing standards. The additional control of Option 1 reflects the use of dual mechanical seals for pumps, and sealed bellows valves. For the purpose of this analysis, this equipment is considered to be leakless (i.e., 100 percent control). However, it is not known if leakless valves/sealed bellows valves will effectively eliminate emissions or if they are available for all sizes and types of equipment in benzene service. Thus, it should be noted that EPA has not concluded that leakless valves/sealed bellows valves will effectively eliminate leaks. Information is needed on the magnitude of emissions released when a sealed bellows valve fails, failure rates of these valves, and appropriate procedures for monitoring valves for failures before any conclusions are made. In addition, a better understanding of the factors affecting equipment leaks and development of new regulatory approaches is needed before significant further reductions in exposures will be assured. Nevertheless, EPA considered Option 1 to determine if it should be selected to provide an ample margin of safety even though there would be technological feasibility issues in implementing this option.

Under Option 1, the estimated MIR would be reduced by roughly a factor of three, and the nationwide incidence would be reduced from 1 case every 5 years (0.2 case/year) under the current NESHAP baseline to 1 case every 10 years (0.1 case/year). As discussed under the "Decision on Acceptable Risk," EPA views the estimate of the MIR for this source category as significantly overstated. The number of people exposed to a risk level between 1 X 10^{-4} and 1 X 10^{-6} would be reduced from about 1 million to 300,000 under Option 1. For the people exposed to these risk levels, the incidence would change from 1 case every 200 years (0.005 case/year) to 1 case every 1,000 years (0.001 case/year) and from 1 case every 25 years (0.04 case/year) to 1 case every 100 years (0.01 case/year), respectively. The number exposed to a risk level less than 1 X 10^{-6} would be the same under Option 1 and the existing standards, with more than 99.5 percent of the total population of 200 million exposed to these risk levels. Most (about 90 percent) of the additional reduction in incidence in Option 1 compared to the existing standards

would occur in the population exposed to risks in the 1 X 10^{-6} range or lower. In addition, benzene concentrations reported to produce noncancer health effects are at least two to three orders of magnitude above the concentrations expected under Option 1 or the existing standards.

Option 1 is estimated to reduce benzene emissions by about 50 percent from the level of the standards. The relative difference between the two control levels may be substantially smaller than this estimate. This is due to the uncertainty that sealed bellows valves would actually achieve the assumed 100 percent reduction in Option 1 and the greater than predicted reductions observed with the current standards' leak detection and repair program. Because of the large uncertainty in the emission levels under the current standards, the likely additional emission reduction cannot be estimated. Implementation of the requirements of Option 1 would increase the annualized control cost by $52.4 million/yr (1979 dollars). (Docket No. A-79-27, Item V-A-1). The majority of the estimated cost is from the cost of sealed bellows valves.

Although Option 1 shows some additional emission and risk reduction may be achievable, the control cost is disproportionately large when compared to the small reductions in risk which could be achieved. If the actual emission reduction were known and used, the option would likely be even less effective. Recognizing the uncertain bias in the emission estimates, the large proportion of the incidence associated with lifetime risks less than 1 X 10^{-6}, the questions regarding technical feasibility, and the costs of additional controls, EPA judged the emission levels associated with the existing NESHAP to protect public health with an ample margin of safety. Therefore, additional control beyond the existing NESHAP is not warranted and will not be required.

Appendix C

Schedule for Source Category MACT Standards

Exhibit C-1
EPA - Clean Air Act - Title III
2-Year MACT Standards

MACT Standard / Source Categories	Number of Source Categories	CFR Subparts	Statutory Date	Administrator Signed Promulgation	Fed Register Publication and Citation	Initial Compliance Date
DRY CLEANING	5	M	11/15/92	09/13/93	09/22/93 (58FR49354)	12/20/93
Commercial dry cleaning dry-to-dry						
Commercial drycleaning transfer machines*						
Commercial drycleaning transfer machines						
Industrial drycleaning dry-to-dry						
Industrial drycleaning transfer machines						
HAZARDOUS ORGANIC NESHAP	1	F, G, H, I	11/15/92	02/28/94	04/22/94 (59FR19402)	10/24/94

Key Legend:
* = denotes area source category
Admin signed date = actual date EPA Administrator signed package